

REMARKS

This Amendment is in response to the Final Office Action mailed February 9, 2005. Claims 5, 7-9 and 36-40 are pending in the application. Claims 5 and 7-9 are withdrawn from consideration as being drawn to non-elected subject matter. By this amendment, Claim 37 is cancelled. Claim 1 is amended to put the claims in better condition for appeal as discussed below. The amendment to Claim 1 is fully supported in the specification as originally filed and does not constitute new matter.

A Notice of Appeal is file herewith.

Rejection of Claims 36-40 under 35 USC § 102(b)

The Examiner rejected Claims 36-40 under 35 U.S.C. 102(b) as being anticipated by Ahmad et al. (WO 92/11046). In particular, the Examiner contends that:

Ahmed et al. disclose a dialysate solution for use in treating patients suffering from kidney failure via dialysis treatment. The dialysate is made according to the needs of the patient undergoing treatment and comprises a mixture of water with about 2.0 to about 3.5 mEq/L of calcium, about 0 to about 1.5 mEq/L of magnesium, about 2 to about 12 mEq/L of citric acid (i.e. citrate), about 0 to about 130 mEq/L to about 150 mEq/L sodium, about 90 to about 120 mEq/L (i.e. sodium chloride) and about 45 mEq/L of bicarbonate. Ahmad further discloses that the dialysate solution may include salts comprising an anion and a cation, wherein the anion may be acetate or lactate. Ahmad further discloses that the method employs a hemodialyzer (i.e. dialyzer) as part of the blood circuit.

The Examiner noted that Applicants' arguments filed November 8th, 2004 were fully considered but they were not persuasive. In particular, the Examiner contends that:

Applicant argues that Ahmad is not prior art under 35 USC 102(b) because it fails to teach a dialysate composition that "requires the presence of magnesium." Applicant further argues that "Ahmad optionally require magnesium" and points to claim 4 that states magnesium is of a concentration "from about 0 to about 1.5 mEq/L" and that "Ahmed can not contain citrate at a concentration level greater than 12 mEq/L" as required. The Examiner respectfully disagrees with the above characterization that Ahmad does not teach the required concentrations of magnesium and citrate. The MPEP 2131.03 sets forth

that prior art that teaches a range within, overlapping, or touching the claimed range anticipates the range. In the instant case, Ahmad sets forth ranges of magnesium to be "from about 0 to about 1.5 mEq/L" and of citrate to be "from about 2 to about 12 mEq/L" of citrate (i.e. citric acid). With respect to the characterization that Ahmad cannot be greater than 12 mEq/L, the examiner respectfully disagrees. "About 12" is widely accepted to mean some degree greater than 12. With respect to the characterization that Ahmad's "from about 0 mEq/L to 1.5 mEq/L" of magnesium results in an optional and not require presence of magnesium, the examiner also respectfully disagrees. "About 0" does not necessarily mean zero or no presence of magnesium. It is widely accepted that "about 0" means at least some degree greater than 0. Clearly these ranges teach a range within, overlapping, or touching the claimed ranges.

Claim 37 is cancelled, thereby rendering moot this rejection with respect thereto. Applicants have amended Claim 36 to include the limitations of cancelled Claim 37. For the following reasons, Applicants respectfully traverse this rejection with respect to Claims 36 and 38-40.

Amended Claim 36 is directed to a method of performing hemodialysis on a post-operative patient suffering from acute kidney failure, wherein the method comprises performing the hemodialysis in a dialyzer with a dialysate composition which is comprised of the following elements at the indicated concentration:

citrate at a concentration ranging from 2.4 to 20 mEq/L,
calcium at a concentration ranging from 2.5 to 5 mEq/L,
magnesium at a concentration ranging from 0.75 to 2 mEq/L, and
a buffering anion selected from the group consisting of acetate, in the form of an acetate salt, and lactate, in the form of a lactate salt, or a mixture thereof, at a concentration ranging from about 0.01 to about 2.5 mEq/L.

Claim 38 is dependent upon Claim 36 and is directed to the method of Claim 36 wherein the composition additionally comprises sodium bicarbonate at a concentration ranging from about 25 to about 40 mEq/L. Claim 39 is dependent upon Claim 36 and is directed the method of Claim 36 wherein the composition additionally comprises sodium chloride at a

concentration ranging from about 110 to about 140 mEq/L. Claim 40 is dependent upon Claim 36 and is directed to the method of Claim 36 wherein the citrate in the composition is in the form of citric acid, sodium dihydrogen citrate, disodium hydrogen citrate, trisodium citrate, potassium dihydrogen citrate or dipotassium hydrogen citrate, or any mixture thereof.

Ahmad does not disclose a method of performing hemodialysis on a post-operative patient suffering from acute kidney failure, wherein the method comprises performing the hemodialysis in a dialyzer with a dialysate composition comprising citrate at a concentration ranging from 2.4 to 20 mEq/L, calcium at a concentration ranging from 2.5 to 5 mEq/L, magnesium at a concentration ranging from 0.75 to 2 mEq/L, and a buffering anion selected from the group consisting of acetate, in the form of an acetate salt, and lactate, in the form of a lactate salt, or a mixture thereof, at a concentration ranging from about 0.01 to about 2.5 mEq/L. In particular, Ahmad does not disclose a dialysate composition which includes a buffering anion selected from the group consisting of acetate, in the form of an acetate salt, and lactate, in the form of a lactate salt, or a mixture thereof, at a concentration ranging from about 0.01 to about 2.5 mEq/L.

In order for a reference to anticipate a claim, the reference must disclose each and every element of the claim. As noted above, Ahmad does not disclose dialysate compositions containing a buffering anion as described in Claim 36. Accordingly, Applicants respectfully submit that Ahmad does not anticipate Claims 36 and 38-40 under 35 U.S.C. 102(b) and therefore respectfully request this rejection of these claims be withdrawn.

Supplemental Information Disclosure Statement

Applicants are filing herewith a Supplemental Information Disclosure Statement to bring to the Examiner's attention the references which were disclosed in a corresponding application, U.S. Serial No. 10/984,374, Applicants' U.S. Patent No. 6,610, 206 and Japanese Patent Application 10/87478, which was cited in a related foreign application.


Conclusion

Applicants submit that Claims 36 and 38-40 are now in condition for allowance. An early Notice of Allowance is respectfully requested.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,
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